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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,246	12/01/2003	Kenneth Newman	03269/100M292-US3	1944

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DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,246	NEWMAN ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-11 and 16-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-11 and 16-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

7.00

DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting Rejections

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 2-11, and 16-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/861239. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in '239 is directed to method of treating acute pain by using the combination of oxycodone/ibuprofen combination, with additional steps of

marketing to the doctor and diagnose of patient. The instant claims herein are generic to the claims in '239

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 2-11, and 16-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-18 of copending Application No. 10/925,783 in view of Cooper et al. (IDS) and Dionne (IDS).

5. '783 claims an analgesic unitary combination of oxycodone and ibuprofen. '783 do not expressly claims the particular amounts herein.

6. However, Cooper et al. and Dionne disclose specific single dose of the combinations herein claimed, i.e., 400mg/5mg and 400mg/10mg (ibuprofen/oxycodone), and the method of using the same for treating postsurgical pain. Partial pain relieve has been observed with 30 minutes for those combination. See, the entire document of Cooper et al. and the abstract, and the figures at page 675 in Dionne.

7. Therefore, it would have been obvious to make the particular unitary dosage herein because the particular combination herein have been known to be useful for treating pain.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections 35 U.S.C. 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2-3, 7-11, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cooper et al. (IDS).

Cooper et al. treated postsurgical patients with a combination of 400 mg of ibuprofen and 5 mg of oxycodone for pain relieving. See the entire document. As to the pain relieving function recited in claims 22 and 23, note, such function would have been inherent to the method employed by Cooper et al. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating or preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use.

10. Claims 2, 3, 5, 7-11, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Dionne (IDS).

11. Dionne discloses a method of treating postsurgical pain by administering to the patient a dose of combination of 400 mg of ibuprofen and 2.5, 5, or 10 mg of oxycodone. For the combinations of 400mg/5mg and 400 mg/10mg (ibuprofen/oxycodone), partial pain relieve has been observed with 30 minutes. See, particularly, the abstract, and the figures at page 675.

Claim Rejections 35 U.S.C. 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 2-11, 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (US 4,569,937, IDS), Cooper et al. (IDS) and Dionne (IDS).

14. Baker et al. teach the synergistic combination of oxycodone (a) and ibuprofen (b), wherein the ratio of a:b is from about 1:6 to 1:400 by weight, and the method of using the same for alleviating pain in mammal. The synergistic composition may be in the form of tablet and capsule. See, particularly, the abstract, the examples in columns 4-8, and the claims. Cooper et al. and Dionne disclose specific single dose of the combinations herein claimed, i.e., 400mg/5mg and 400mg/10mg (ibuprofen/oxycodone), and the method of using the same for treating postsurgical pain. Partial pain relieve has been observed with 30 minutes for those combination. See, the entire document of Cooper et al. and the abstract, and the figures at page 675 in Dionne.

15. The cited references do not teach expressly a unitary dosage in the form of tablet or capsule comprising the combination 400mg/5mg or 400mg/10mg (ibuprofen/oxycodone), or the method of using such unitary dosage for pain relieving.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the particular unitary dosage herein and to use the same for treating acute pain.

A person of ordinary skill in the art would have been motivated to make the particular unitary dosage herein and to use the same for treating acute pain because the particular dosage amounts

are known to be useful for treating pain and the combination dosage are known to be made into tablet and capsule. Pain due to surgical operation would be considered as acute pain. Further, since the method are known to be effective quickly after the administration of the dose, one of ordinary skill in the art would have been motivated to use the method for treating acute pain. Further, The optimization of a result effective parameter, e.g., effective amounts of a therapeutical agent, or its releasing profile in a dosage form, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617